

Notice of Allowability

Application No.

09/902,086

Applicant(s)

GEREG, GEORGE W.

Examiner

Art Unit

Stephen J. Lechert Jr.

1732

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address--

All claims being allowable, PROSECUTION ON THE MERITS IS (OR REMAINS) CLOSED in this application. If not included herewith (or previously mailed), a Notice of Allowance (PTOL-85) or other appropriate communication will be mailed in due course. **THIS NOTICE OF ALLOWABILITY IS NOT A GRANT OF PATENT RIGHTS.** This application is subject to withdrawal from issue at the initiative of the Office or upon petition by the applicant. See 37 CFR 1.313 and MPEP 1308.

1. ☒ This communication is responsive to IDS of 4/8/2002 and the filing date of 7-11-2001.
2. ☒ The allowed claim(s) is/are 14-18, re-numbered as claims 1-5 respectively.
3. ☒ The drawings filed on 11 July 2001 are accepted by the Examiner.
4. ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 - a) ☐ All b) ☐ Some* c) ☐ None of the:
 1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this national stage application from the International Bureau (PCT Rule 17.2(a)).
 - * Certified copies not received: _____.
5. ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.
 - (a) ☐ The translation of the foreign language provisional application has been received.
6. ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

Applicant has THREE MONTHS FROM THE "MAILING DATE" of this communication to file a reply complying with the requirements noted below. Failure to timely comply will result in ABANDONMENT of this application. **THIS THREE-MONTH PERIOD IS NOT EXTENDABLE.**

7. ☐ A SUBSTITUTE OATH OR DECLARATION must be submitted. Note the attached EXAMINER'S AMENDMENT or NOTICE OF INFORMAL PATENT APPLICATION (PTO-152) which gives reason(s) why the oath or declaration is deficient.
8. ☐ CORRECTED DRAWINGS (as "replacement sheets") must be submitted.
 - (a) ☐ including changes required by the Notice of Draftsperson's Patent Drawing Review (PTO-948) attached
 - 1) ☐ hereto or 2) ☐ to Paper No. _____.
 - (b) ☐ including changes required by the proposed drawing correction filed _____, which has been approved by the Examiner.
 - (c) ☐ including changes required by the attached Examiner's Amendment / Comment or in the Office action of Paper No. _____.

Identifying indicia such as the application number (see 37 CFR 1.84(c)) should be written on the drawings in the front (not the back) of each sheet. Replacement sheet(s) should be labeled as such in the margin according to 37 CFR 1.121(d).

9. ☐ DEPOSIT OF and/or INFORMATION about the deposit of BIOLOGICAL MATERIAL must be submitted. Note the attached Examiner's comment regarding REQUIREMENT FOR THE DEPOSIT OF BIOLOGICAL MATERIAL.

Attachment(s)

- | | |
|--|---|
| 1 <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 5 <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 2 <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 6 <input checked="" type="checkbox"/> Interview Summary (PTO-413), Paper No. _____ |
| 3 <input checked="" type="checkbox"/> Information Disclosure Statements (PTO-1449 or PTO/SB/08), Paper No. _____ | 7 <input checked="" type="checkbox"/> Examiner's Amendment/Comment |
| 4 <input type="checkbox"/> Examiner's Comment Regarding Requirement for Deposit of Biological Material | 8 <input checked="" type="checkbox"/> Examiner's Statement of Reasons for Allowance |
| | 9 <input type="checkbox"/> Other _____ |

Stephen J. Lechert Jr.
Primary Examiner
Art Unit: 1732

DETAILED ACTION

1. Restriction to one of the following inventions is required under 35 U.S.C. 121:
 - I. Claims 1-13, drawn to a press punch, classified in class 425, subclass 352.
 - II. Claims 14-18, drawn to a method of compacting a drug, classified in class 264, subclass 40.1.

The inventions are distinct, each from the other because of the following reasons:

2. Inventions II and I are related as process and apparatus for its practice. The inventions are distinct if it can be shown that either: (1) the process as claimed can be practiced by another materially different apparatus or by hand, or (2) the apparatus as claimed can be used to practice another and materially different process. (MPEP § 806.05(e)). In this case the process can be performed by an apparatus materially different than that of the group I apparatus, for example, the method requires a comminuting apparatus for comminuting step in the method and the press punch of the group I claims does not require the comminuting means. The press punch of the Group I claims can be used to fabricate compacts material different than the drug formulations of the method claims.
3. Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification, restriction for examination purposes as indicated is proper.

4. Because these inventions are distinct for the reasons given above and the search required for Group I is not required for Group II, restriction for examination purposes as indicated is proper.
5. During a telephone conversation with Mr. Bottino on 12/3/2003 a provisional election was made with traverse to prosecute the invention of Group II, claims 14-18. Affirmation of this election must be made by applicant in replying to this Office action. Claims 1-13 have been withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to a non-elected invention.
6. Action on the merits of claims 14-18 follows:
7. Claims 14-18 are free of the prior art.
8. An examiner's amendment to the record appears below. Should the changes and/or additions be unacceptable to applicant, an amendment may be filed as provided by 37 CFR 1.312. To ensure consideration of such an amendment, it **MUST** be submitted no later than the payment of the issue fee.

Authorization for this examiner's amendment was given in a telephone interview with Mr. Bottino on December 3, 2003.

The application has been amended as follows:

In the Title:

Delete "Apparatus and"

In the Claims:

Delete claims 1-13 without prejudice, applicant reserves the right to file a divisional application.

9. The following is an examiner's statement of reasons for allowance:

The invention relates to a method of evaluating new drug formulations for fabrication by compaction comprising steps determining the flow properties of the new drug formulation, compacting the new drug formulation, preparing granules from the compact by comminuting the new drug formulation which do not demonstrate all three of the following flow properties: (a) a Carr Index below 15%; (2) a static angle of repose between 20° and 40°; (3) gravity free flow; characterizing the flow properties of the granules product, recompression of the granules which demonstrate all three of the flow properties and then evaluating the recompression for acceptable hardness of the new drug formulation, the process as claimed has not been taught either singularly or in combination by the prior art.

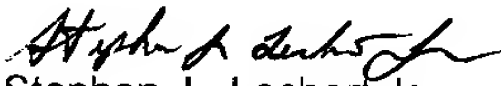
Any comments considered necessary by applicant must be submitted no later than the payment of the issue fee and, to avoid processing delays, should preferably accompany the issue fee. Such submissions should be clearly labeled "Comments on Statement of Reasons for Allowance."

10. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Stiel and Serpelloni et al. show methods of making compacted drug formulations but does not teach how to evaluate the drug formulations by comminuting a compacted drug formulation and then evaluating the flow properties of the granules based on the Carr Index, static angle of repose and gravity free flow and then recompacting the drug after evaluating step.

11. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Stephen J. Lechert Jr. whose telephone number is 703-305-6156. The examiner can normally be reached on 9:30-6:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael P. Colaianni can be reached on 703-305-5493. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9310.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-306-5665.


Stephen J. Lechert Jr.
Primary Examiner
Art Unit 1732